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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/626,379	AMIDON ET AL.	
	Examiner	Art Unit	
	ABIGAIL FISHER	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) *31-36 and 42-47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30 and 37-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/29/03, 9/26/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-47 are pending.

Election/Restrictions

Applicant's election of Group I in the reply filed on January 28 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election **without** traverse (MPEP § 818.03(a)). Claims 1-47 are pending in the application. Claims 31-36 and 42-47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on January 28 2008. Accordingly, claims 1-30 and 37-41 are being examined on the merits herein.

Abstract

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because it contains legal phraseology such as comprises in line 2 of the abstract. Correction is required. See MPEP § 608.01(b).

Claim Interpretation

Claim 1 as written can be interpreted in two different ways. One interpretation is where a matrix which comprises a hydrophilic polymer and a starch, has a tensile strength of at least about 0.15 kN cm^{-2}. The other interpretation is where the starch has a tensile strength of at least about 0.15 kN cm^{-2}. Art rejections will be applied to both interpretations.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-30 and 37-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3, 37 and 40 are directed to a tensile strength of **at least about** 0.15 (or 0.175 or 0.2) kN cm^{-2}. The claims as written are vague and indefinite. It is unclear what constitutes the lower limit of the tensile strength. Is the lower limit at least 0.15 or is it about 0.15?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 13-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Kitamori et al. (US Patent No. 4036948). Kitamori et al. discloses in Example 6 a tablet comprising hydroxypropyl starch (a hydrophilic polymer), corn starch (a starch), L-ascorbic acid (an active pharmaceutical agent) with a tensile strength of 18.7 kg/cm^2 (0.187 kN/cm^2). A tensile strength of 0.187 kN/cm^2 is about 0.2 kN/cm^2 and therefore anticipates instant claim 3. L-Ascorbic acid, as evidenced by the Merck Index (thermerckinex.cambridgesoft.com, 2006) has a solubility of 1g/3mL which is not less than 10 mg/mL.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-14, 20-22, 26, 29, 37, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vandecruys et al. (WO 00/59477, cited on PTO Form 1449).

Applicant Claims

Applicant claims a composition comprising an active pharmaceutical agent having a solubility not less than about 10 mg/mL, dispersed in a matrix comprising a hydrophilic polymer and a starch having a tensile strength of about 0.15 kN/cm^2.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The formulations of the invention comprise active ingredients, viscous hydrophilic polymer(s), pregelatinized starch, and pharmaceutically acceptable formulating agents

(page 20-21, lines 21-36 and 1-25). One formulation is where the hydrophilic polymer is hydoxypropyl cellulose and is present in an amount from 25-62% (page 21, line 22). This percentage anticipates instant claims 10 and 11. Other percentages disclosed are from 0.01-80% (page 20, line 23). The pregelatinized starch is present in an amount from 0.01 -<80% (page 20, line 24). It is disclosed that the most preferred hydrophilic polymers are hydroxypropyl methylcellulose and hydroxypropyl cellulose (page 12, lines 12-13). It is disclosed that the formulations of the invention are useful for administering one or more active ingredients (page 6, lines 31-32). Suitable active ingredients include antidepressants such as reboxetine (page 7, line 16), setraline (page 7, line 18), or 3-[2-[3,4-dihydrobenzofuro[3,2-c]pyridine-2(1H)-yl]ethyl]-2-methyl-4H-pyrido[1,2-a]pyrimidin-4-one (page 7, lines 18-19 and examples 3-4), and their pharmaceutically acceptable salts or their stereochemically isomeric forms..

It is disclosed that the tablets of the invention are preferably film coated. The coatings can serve purposes such as improving stability and shelf-life or improving taste or ease to which the tablet can be swallowed (page 23, lines 30-33).

It is disclosed that the formulation is prepared by mixing one or more actives, pregelatinized starch, one or more hydrophilic polymers, and optionally some or all of the pharmaceutically acceptable formulating agents. The mixture is then tabletted using direct compression (page 22, liens 37-38). The resulting tablets are manufactured from a homogenous dispersion of the above mentioned ingredients (page 23, lines 19-20).

Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)

While Vandecruys et al. exemplifies utilizing antidepressants in the tablet formulations of the invention, Vandecruys et al. does not exemplify utilizing the antidepressants reboxetine or a combination of reboxetine and sertraline. However, Vandecruys et al. does indicate that reboxetine and sertraline are suitable.

Vandecruys et al. does not exemplify the claimed starch or hydrophilic polymer ranges. However, Vandecruys et al. does disclose overlapping ranges.

Vandecruys et al. does not specify selecting by a suitable test a starch.

Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to utilize reboxetine or its salt or enantiomer thereof as the active ingredient in the invention of Vandecruys et al. One of ordinary skill in the art would have been motivated to utilize reboxetine, an antidepressant, because Vandecruys et al. exemplifies utilizing as the active ingredient a different antidepressant, 3-[2-[3,4-dihydrobenzofuro[3,2-c]pyridine-2(1H)-yl]ethyl]-2-methyl-4H-pyrido[1,2-a]pyrimidin-4-one. Therefore it would have been obvious to one of ordinary skill in the art to substitute one known antidepressant for another antidepressant. One of ordinary skill in the art would have been motivated to select reboxetine as the antidepressant from all known other antidepressants because Vandecruys et al. indicate that it is suitable. One of ordinary skill in the art would have been motivated to utilize the salt or enantiomer because Vandecruys et al. discloses

that salts and stereochemically isomeric forms are suitable. It would have been obvious to one of ordinary skill in the art to pursue known options within his or her technical grasp, specifically salts or stereochemically isomeric forms of the active ingredients.

It would have been obvious to one of ordinary skill in the art to utilize reboxetine and sertraline as the active ingredients in the invention of Vandecruys et al. One of ordinary skill in the art would have been motivated to utilize this combination because Vandecruys et al. discloses that one or more active ingredients can be utilized. Additionally Vandecruys et al. exemplifies utilizing an antidepressant as the active. Therefore one of ordinary skill in the art would have been motivated to replace one antidepressant for another antidepressant, such as reboxetine or sertraline.
As a general principle it is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose, the idea of combining them flows logically from their having been individually taught in the prior art. See *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) **MPEP 2144.06.**

Therefore, absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Regarding the limitation of the tensile strength, Vandecruys et al. is silent as to the tensile strength of the starch. However, the starches utilized Vandecruys et al. are

the same starches claimed in the instant application, pregelatinized starches. Therefore, absent evidence to the contrary, the examiner believes that the starches disclosed by Vandecruys et al. would have the same if not similar tensile strength.

Regarding the claimed ranges of starch (claims 4-7) and the claimed ranges of hydrophilic polymer (claim 12), Vandecruys et al. discloses overlapping ranges. In the case where in the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. **See MPEP 2144.05 [R-5]**

Regarding claim 37, it would have been obvious to one of ordinary skill in the art to choose a particular starch or a particular active pharmaceutical agent based on the desired properties of the tablet. The only starch utilized by Vandecruys et al. is the preferred starch of the instant application. The selection of a suitable starch as well as the selection of an active pharmaceutical is an implicit step in the formulation of an active-containing tablet. Therefore, the process for preparing the composition of Vandecruys et al. is the same as that instantly claimed.

Claims 15-19, 23-25, 30, 38-39 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vandecruys et al. in view of Rogosky et al. (US PGPUB No. 2002/0010216).

Applicant Claims

Applicant claims that active pharmaceutical agent is therapeutically effective at a daily dose not greater than 100 mg (50 or 25 or 10 or 5mg).

Applicant claims that the pharmaceutical agent is (S,S)-reboxetine succinate.

Applicant claims that the tablet comprises about 0.2 to about 15 mg (about 1 to about 12 mg) reboxetine per tablet.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Vandecruys et al. are set forth above. Vandecruys et al. indicates that reboxetine and sertraline are suitable active ingredients.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Vandecruys et al. does not specify that the reboxetine is (S,S)-reboxetine succinate. Vandecruys et al. does not specify the dosage of reboxetine that are suitable. Vandecruys et al. does not specify the combination of (S,S)-reboxetine succinate and sertraline. However, these deficiencies are cured by Rogosky et al.

Rogosky et al. indicates that when the preferred compound of use is based, for example reboxetine, pharmaceutically acceptable salts include succinate (paragraph 0030). It is also indicated that the (S,S) enantiomer is particular preferred (paragraph 0031). The dosage of reboxetine is from about 0.1 mg to about 10 mg. The daily dosage is administered in one, two, or more times a day (paragraph 0033).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to combine the teachings of Vandecruys et al. and Rogosky et al. and utilize (S,S)-reboxetine succinate as the active ingredient. One of ordinary skill in the art would have been motivated to utilize (S,S)-reboxetine succinate because Rogosky et al. indicates that the (S,S) enantiomer is the preferred enantiomers. Additionally Rogosky et al. indicates that one

type of pharmaceutical salt of reboxetine that is suitable is succinate. It would have been obvious to one of ordinary skill in the art to pursue known options within his or her technical grasp, specifically the pharmaceutically acceptable salts and (S,S) enantiomer of reboxetine.

It would have been obvious to one of ordinary skill in the art to utilize (S,S)-reboxetine succinate and sertraline as the active ingredients in the invention of Vandecruys et al. One of ordinary skill in the art would have been motivated to utilize this combination because Vandecruys et al. discloses that one or more active ingredients can be utilized. Additionally Vandecruys et al. exemplifies utilizing an antidepressant as the active. Therefore one of ordinary skill in the art would have been motivated to replace one antidepressant for another antidepressant, such as reboxetine or sertraline. As a general principle it is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose, the idea of combining them flows logically from their having been individually taught in the prior art. See *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) **MPEP 2144.06.**

It would have been obvious to one of ordinary skill in the art to combine the teachings of Vandecruys et al. and Rogosky et al. and utilize a dosage of reboxetine from 0.1 to 10 mg. One of ordinary skill in the art would have been motivated to select one of these particular dosages because Rogosky et al. indicates that these are the dosages that are effective.

Therefore, absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vandecruys et al. in view of Glinecke et al. (US Patent No. 6451343).

Applicant Claims

Applicant claims that the coating on the tablet is a release-controlling layer and constitutes about 1 to about 15% by weight of the tablet.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Vandecruys et al. are set forth above. Vandecruys et al. indicates that the tablets can be coated.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Vandecruys et al. does not specify that the coating is a release-controlling. However, this deficiency is cured by Glinecke et al.

Glinecke et al. discloses that controlled release dosage forms are advantageous. Controlled release formulations requires dosing only once a day, this type of formulation is likely to improve compliance in patient population (column 1, lines 29-32). The

controlled release coatings are polymer coatings made from ethylcellulose and opadry clear in 4-5% by weight of the tablet (example 3). .

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to combine the teachings of Vandecruys et al. and Glinecke et al. and utilize a controlled release formulation in an amount from 4-5% by weight of the tablet. One of ordinary skill in the art would have been motivated to utilize this type of coating because it is known in the art that controlled release formulations using coatings improve patient compliance by providing once a day formulations. It would have been obvious to one of ordinary skill in the art to utilize the coating in 4-5% by weight of the tablet because Glinecke et al. discloses that is an acceptable percentage for these types of controlled release coatings.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated

by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-21 and 26-29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 10626166. Although the conflicting claims are not identical, they are not patentably distinct from each other because they overlap in scope.

The instant application claims a sustained-release pharmaceutical composition comprising an active pharmaceutical agent having solubility not less than 10 mg/ml dispersed in a matrix comprising a hydrophilic polymer an a starch having a tensile strength of at least about 0.15 kN/cm^2.

Copending '166 claims a sustained-release pharmaceutical composition comprising a water-soluble salt of pramipexole dispersed in a matrix comprising a hydrophilic polymer and a starch having a tensile strength of at least about 0.15 kN/cm^2. Copending '166 claims all the instant limitations in the dependent claims.

The difference between the instant application and '166 is that '166 claims a specific type of active pharmaceutical agent.

Therefore, both the instant application and '166 are directed to similar subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-21 and 37 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 and 28 of copending Application No. 10/821646. Although the conflicting claims are not identical, they are not patentably distinct from each other because they overlap in scope.

The instant application claims a sustained-release pharmaceutical composition comprising an active pharmaceutical agent having solubility not less than 10 mg/ml dispersed in a matrix comprising a hydrophilic polymer an a starch having a tensile strength of at least about 0.15 kN/cm^2.

Copending '646 claims a sustained-release pharmaceutical composition comprising a pharmaceutical agent of a particular formula, with a specific species claimed is sumanirole maleate, dispersed in a matrix comprising a hydrophilic polymer and a starch having a tensile strength of at least about 0.15 kN/cm^2. Copending '646 claims all the instant limitations in the dependent claims.

The difference between the instant application and '646 is that '646 claims a specific type of active pharmaceutical agent.

Therefore, both the instant application and '646 are directed to similar subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 26-29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 13 of copending Application No. 10871646 in view of Vandecruys et al. or Glinecke et al.

The instant application claims a sustained-release pharmaceutical composition comprising an active pharmaceutical agent having solubility not less than 10 mg/ml dispersed in a matrix comprising a hydrophilic polymer an a starch having a tensile strength of at least about 0.15 kN/cm^2. The tablet further comprises a coating. The coating as claimed is either release-controlling or is a non-functional coating.

Copending '646 claims a sustained-release pharmaceutical composition comprising a pharmaceutical agent of a particular formula, with a specific species claimed is sumanirole maleate, dispersed in a matrix comprising a hydrophilic polymer and a starch having a tensile strength of at least about 0.15 kN/cm^2.

Copending '646 does not claim a coating. However, this deficiency is cured by either Vandecruys et al. or Glinecke et al.

Vandecruys et al. discloses that tablets can be coated with films that improve the taste of the tablet or the ease with which they can be swallowed. Additionally the coatings my improve stability and shelf-life of the tablet (page 23, lines 30-33).

Glinecke et al. discloses that controlled release dosage forms are advantageous. Controlled release formulations requires dosing only once a day, this type of formulation

is likely to improve compliance in patient population (column 1, lines 29-32). The controlled release coatings are polymer coatings made from ethylcellulose and opadry clear in 4-5% by weight of the tablet (example 3).

It would have been obvious to one of ordinary skill in the art to combine the teachings of Copending '646 and either Vandecruys et al. or Glinecke et al. and utilize either a film coating or a controlled release coating depending on the desired formulation. One of ordinary skill in the art would have been motivated to combine the teachings of Copending '646 and Vandecruys et al. if a desire to improve the ease to which the tablets can be swallowed was required. One of ordinary skill in the art would have been motivated to combine the teachings of Copending '646 and Glinecke et al. in order to improve patient compliance by providing a dosage formulation that required only once a day dosing.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

This is a provisional obviousness-type double patenting rejection.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Abigail Fisher
Examiner
Art Unit 1616

AF

/Sharmila Gollamudi Landau/

Primary Examiner, Art Unit 1611